

occur. Documentation of such reports shall be retained in MDR files for time periods specified in § 803.18.

(2) The manufacturer or importer determines that the device was manufactured or imported by another manufacturer or importer. Any reportable event information that is erroneously sent to a manufacturer or importer shall be forwarded to FDA, with a cover letter explaining that the device in question was not manufactured or imported by that firm.

[60 FR 63597, Dec. 11, 1995, as amended at 65 FR 4120, Jan. 26, 2000]

Subpart C—User Facility Reporting Requirements

§ 803.30 Individual adverse event reports; user facilities.

(a) *Reporting standard.* A user facility shall submit the following reports to the manufacturer or to FDA, or both, as specified below:

(1) *Reports of death.* Whenever a user facility receives or otherwise becomes aware of information, from any source, that reasonably suggests that a device has or may have caused or contributed to the death of a patient of the facility, the facility shall as soon as practicable, but not later than 10 work days after becoming aware of the information, report the information required by § 803.32 to FDA, on FDA Form 3500A, or an electronic equivalent as approved under § 803.14, and if the identity of the manufacturer is known, to the device manufacturer.

(2) *Reports of serious injury.* Whenever a user facility receives or otherwise becomes aware of information, from any source, that reasonably suggests that a device has or may have caused or contributed to a serious injury to a patient of the facility, the facility shall, as soon as practicable but not later than 10 work days after becoming aware of the information, report the information required by § 803.32, on FDA Form 3500A or electronic equivalent, as approved under § 803.14, to the manufacturer of the device. If the identity of the manufacturer is not known, the report shall be submitted to FDA.

(b) *Information that is reasonably known to user facilities.* User facilities must provide all information required

in this subpart C that is reasonably known to them. Such information includes information found in documents in the possession of the user facility and any information that becomes available as a result of reasonable followup within the facility. A user facility is not required to evaluate or investigate the event by obtaining or evaluating information that is not reasonably known to it.

§ 803.32 Individual adverse event report data elements.

User facility reports shall contain the following information, reasonably known to them as described in 803.30(b), which corresponds to the format of FDA Form 3500A:

(a) Patient information (Block A) shall contain the following:

- (1) Patient name or other identifier;
- (2) Patient age at the time of event, or date of birth;
- (3) Patient gender; and
- (4) Patient weight.

(b) Adverse event or product problem (Block B) shall contain the following:

- (1) Identification of adverse event or product problem;
- (2) Outcomes attributed to the adverse event, e.g., death; or serious injury, that is:
 - (i) Life threatening injury or illness;
 - (ii) Disability resulting in permanent impairment of a body function or permanent damage to a body structure; or
 - (iii) Injury or illness that requires intervention to prevent permanent impairment of a body structure or function;
- (3) Date of event;
- (4) Date of report by the initial reporter;
- (5) Description of event or problem, including a discussion of how the device was involved, nature of the problem, patient followup or required treatment, and any environmental conditions that may have influenced the event;
- (6) Description of relevant tests including dates and laboratory data; and
- (7) Description of other relevant history including pre-existing medical conditions.

(c) Device information (Block D) shall contain the following:

- (1) Brand name;